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#23

In Re: Patent Term Extension Application for
U.S. Patent No. 4,338,325
Inventors: Roy A. Johnson, et al.
Assignee: The Upjohn Company

U.S. Patent No. 4,883,812 has been extended under 35 U.S.C. § 156 based upon the regulatory review period of the product FLOLAN[®], pursuant to an election by applicant Glaxo Wellcome Inc.

Only one patent can be extended under 35 U.S.C. § 156 based upon a single regulatory review period of a product. See 35 U.S.C. § 156(c)(3). Since the '812 patent has been extended based upon the regulatory review period of the product FLOLAN[®], the application for patent term extension, filed November 16, 1995 and requesting extension of U.S. Patent No. 4,338,812 based upon said regulatory review period, cannot be granted.

Accordingly, the application for patent term extension for U.S. Patent No. 4,338,812 is dismissed.

A single request for reconsideration of this final determination may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are applicable to this time period. See 37 CFR 1.750.

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Tyson
Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

RE: FLOLAN[®]
FDA Docket No.: 95E-0418